

REMARKS

I. Status Summary

Claims 1-16, 18, and 20-43 are pending in the present application. Claims 2-15 and 30-43 have been withdrawn as being directed to non-elected subject matter. Claims 1, 16, 18, 20-27, and 29 have been rejected by the U.S. Patent and Trademark Office (hereinafter the "Patent Office"). Claim 28 has been made the subject of an objection.

Claims 23 and 28 have been amended. New claim 44 has been added. Support for the amendments and new claim can be found throughout the specification and claims as filed. No new matter has been added.

Withdrawn claims 2-15 and 30-43 have been canceled herein without prejudice. Applicants respectfully reserve the right to file one or more divisional patent applications directed to the subject matter of canceled claims 2-15 and 30-43.

Reconsideration of the application as amended and further in view of the remarks set forth herein below is respectfully requested.

II. Response to Rejections under 35 U.S.C. § 112, Second Paragraph

Claim 23 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. More particularly, the Patent Office contends that claim 23 lacks antecedent basis in claim 1. The Patent Office contends that the term "prodrug" is not limited to prodrugs of amidino and guanidino, but can include any prodrug presently known.

After careful consideration of the rejection and of the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, without acquiescing to the rejection and in an effort to expedite allowance of the instant application, applicants respectfully submit that claim 23 has been amended herein to recite "wherein R₅ is selected from hydroxyl, alkoxyl and acyloxy." Support for the amendment can be found in claims 1 and 23 as originally filed. Additional support can be found in the instant specification, for example, at page 33, lines 13-18, which recites that prodrugs of amidino or guanidino groups can be

prepared by introducing an oxygen-containing moiety (e.g., hydroxyl or alkoxy) at a nitrogen atom.

Accordingly, applicants respectfully submit that the Patent Office remarks with regard to the term “prodrugs” has been addressed.

Applicants respectfully submit that claim 23 meets the requirements of 35 U.S.C. § 112, second paragraph. Therefore, applicants respectfully request that the rejection of claim 23 under 35 U.S.C. § 112, second paragraph, be withdrawn and further ask that claim 23 be allowed at this time.

III. Response to Rejections under 35 U.S.C. § 103(a) over Mallena in view of Goldberg

Claims 1, 16, 18, 20-22, 24-27, and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mallena et al. (*J. Am. Chem. Soc.*, September 2004, 126(42), 13659-13669; hereinafter “Mallena”) in view of U.S. Patent No. 2,641,601 to Goldberg et al. (hereinafter “Goldberg”). The Patent Office contends that Mallena teaches diamidine compounds useful in treating parasitic diseases and teaches compounds such as DB818 and DB75. While the Patent Office concedes that Mallena does not disclose that DB818 and DB75 are useful for treating trichomoniasis, the Patent Office contends that Goldberg teaches that 2,5-diphenylfurans are useful as anti-trichomonas compounds. Thus, the Patent Office contends that it would be obvious to one skilled in the art to prepare products disclosed in Mallena with the expectation of obtaining products useful in treating trichomoniasis.

After careful consideration of the rejection and of the Patent Office’s comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, applicants respectfully submit that the instantly claimed subject matter relates to the use of compounds of Formula (I) in treating trichomoniasis infections. The compounds of Formula (I) include a group “L” that is a thiophenyl group, a group “Ar₁” that is a phenyl group, and a group “Ar₂” that is a benzimidazole group.

Applicants respectfully submit that Goldberg at best relates to compounds including a diphenyl furan core structure. Goldberg does not describe or suggest activity for a compound of Formula (I) as recited in claim 1.

Applicants respectfully submit that Mallena describes a single compound related to Formula (I) as presently recited in claim 1, i.e., 2-(4-Amidinophenyl)-5-[2-(5-amidinobenzimidazolyl)]thiophene, also known as DB818. Further, applicants respectfully submit that Mallena generally relates to minor groove DNA binding, but does not provide any data related particularly to activity of compounds against trichomoniasis infections.

Applicants respectfully submit that U.S. Provisional Patent Application Serial No. 60/551,089 (hereinafter "the '089 Application"), filed on March 8, 2004, to which the present U.S. patent application ultimately claims priority describes compounds of Formula (IV) for use in treating trichomoniasis infections. See the '089 Application, e.g., claim 26. Formula (IV) of the '089 Application is appreciably commensurate in scope with Formula (IV) of the instant application as recited in instant claim 16. Formula (IV) of the '089 Application also overlaps with Formula (I) of instant claim 1 as presently recited. Further, applicants respectfully submit that DB818 and its anti-trichomoniasis activity were described in the '089 Application. See the '089 Application, e.g., at page 33, Scheme 1 and page 35, Table 1. See also, the '089 Application, claim 29. Thus, in particular, applicants respectfully submit that at least instant claim 21, which recites 2-(4-Amidinophenyl)-5-[2-(5-amidinobenzimidazolyl)]thiophene has support in the provisional patent application and should be accorded a priority date prior to Mallena. Therefore, applicants respectfully request that the rejection at least with regard to claim 21 be withdrawn and that claim 21 be allowed at this time.

Applicants further respectfully submit that, as described in the attached Declaration Pursuant to 37 C.F.R. § 1.132, the disclosure related to DB818 in Mallena is based on and/or derived from the applicants' own work. As described in Manual of Patent Examining Procedure § 715.01(c) and 716.10, referring e.g., to *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982), unless it is a statutory bar, a rejection based on a publication can be overcome by an affidavit or declaration by the applicant establishing that the publication is describing the applicant's own work or was derived from the applicant. Thus, it is respectfully requested that Mallena be withdrawn as a reference and that the rejection of claims 1, 16, 18, 20-22, 24-27, and 29 under 35 U.S.C. § 103(a) over Mallena in view of Goldberg be withdrawn. Applicants respectfully

submit that claims 1, 16, 18, 20-22, 24-27, and 29 are in condition for allowance and respectfully request a Notice of Allowance to that effect.

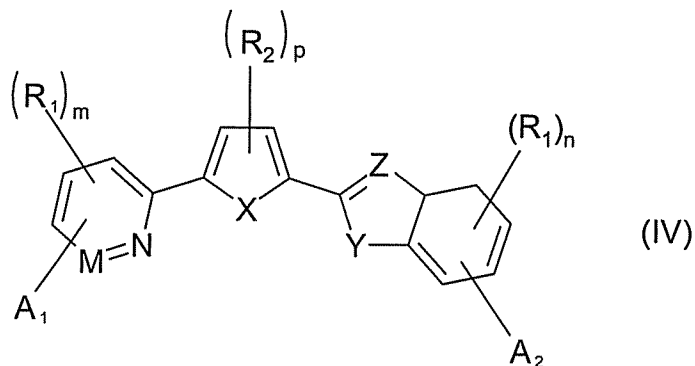
IV. Claim Objections/Allowable Subject Matter

The Patent Office has indicated that claim 28 is objected to for being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

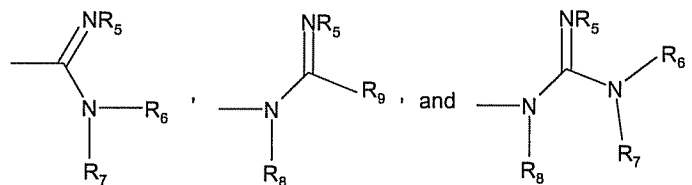
Applicants gratefully acknowledge the Patent Office's indication regarding the potential allowability of claim 28. Applicants respectfully submit that claim 28 has been amended herein to independent form. Support for the amendment can be found in claims 1 and 28 as originally filed. Accordingly, applicants respectfully submit that claim 28 is in condition for allowance and respectfully request a Notice of Allowance to that effect.

V. New Claim

New claim 44 recites a method of treating a trichomoniasis infection in a subject in need thereof, the method comprising administering to the subject an effective amount of a compound of Formula (IV):



wherein: M and N are each CH; Z is N; Y is NH; m is an integer from 0 to 2; n is an integer from 0 to 3; p is an integer from 0 to 2; each R_1 and R_2 is independently selected from the group consisting of alkyl, halo, hydroxyl, alkoxyl, aryloxy, and aralkyloxy; X is S; and A_1 and A_2 are each independently selected from the group consisting of:



wherein: R₅, R₆, R₇, R₈, and R₉ are each independently selected from the group consisting of H, alkyl, cycloalkyl, aryl, aralkyl, hydroxyl, alkoxyl, hydroxyalkyl, hydroxycycloalkyl, alkoxycycloalkyl, aminoalkyl, acyloxyl, alkylaminoalkyl, and alkoxycarbonyl; or R₅ and R₆ together represent a C₂ to C₁₀ alkyl, C₂ to C₁₀ hydroxyalkyl, or C₂ to C₁₀ alkylene; or a pharmaceutically acceptable salt thereof.

Support for new claim 44 can be found in claims 1 and 16 as originally filed. No new matter has been added. Applicants respectfully submit that new claim 44 is in condition for allowance and respectfully request a Notice of Allowance to that effect.

CONCLUSIONS

Should there be any minor issues outstanding in this matter, the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

Date: 02/23/2011

By: Arles A. Taylor, Jr.

Arles A. Taylor, Jr.
Registration No. 39,395
Customer No. 25297
(919) 493-8000

1523/2 PCT/US

AAT/ALO/cam

Enclosures